



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-N-0008]

Blood Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) announces a forthcoming public advisory committee meeting of the Blood Products Advisory Committee (BPAC). The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues related to blood and products derived from blood. Matters considered at the meeting will include current strategies to reduce the risk of Zika virus (ZIKV) transmission by blood and blood components, an update on the Transfusion Transmissible Infections Monitoring System (TTIMS), and testing blood donations for hepatitis B surface antigen. The meeting will be open to the public.

DATES: The meeting will be held on April 2, 2020, from 8:30 a.m. to 3:45 p.m. and April 3, 2020, from 8:30 a.m. to 12:30 p.m.

ADDRESSES: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993-0002. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For security information, please refer to <https://www.fda.gov/about-fda/white-oak-campus-information/public-meetings-fda-white-oak-campus>. Answers to commonly asked questions including information regarding special

accommodations due to a disability, visitor parking, and transportation may be accessed at:
<https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

For those unable to attend in person, the meeting will also be webcast and will be available at the following link: <https://collaboration.fda.gov/bpacapril20/>.

FOR FURTHER INFORMATION CONTACT: Christina Vert or Joanne Lipkind, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 6268, Silver Spring, MD 20993-0002, 240-402-8054, christina.vert@fda.hhs.gov, or 240-402-8106, joanne.lipkind@fda.hhs.gov, respectively, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the *Federal Register* about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's website at <https://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting. For those unable to attend in person, the meeting will also be available via webcast. The webcast will be available at the following link for both days: <https://collaboration.fda.gov/bpacapril20/>.

SUPPLEMENTARY INFORMATION:

Agenda: On April 2, 2020, in the morning, the BPAC will meet in open session to discuss and make recommendations on strategies to reduce the risk of ZIKV transmission by blood and blood components. The committee will discuss whether universal testing of blood donations for ZIKV is an appropriate strategy considering the decline of ZIKV cases in the United States and worldwide. In the afternoon, the committee will meet in open session to hear

an update on the TTIMS. Sponsored by the FDA, the National Institutes of Health National Heart, Lung and Blood Institute, and the Department of Health and Human Services Office of the Assistant Secretary for Health, TTIMS collects incidence, prevalence and risk factor data for certain transfusion-transmitted infections, including human immunodeficiency virus, in U.S. blood donations. On April 3, 2020, the committee will meet in open session to discuss and make recommendations on testing for hepatitis B surface antigen (HBsAg) in blood donations. The committee will discuss whether testing for HBsAg can be discontinued considering the sensitivity of hepatitis B virus nucleic acid testing and hepatitis B anti-core testing of blood donations in the United States.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background material is available at <https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before March 25, 2020. On April 2, 2020, oral presentations from the public will be scheduled between approximately 10:50 a.m. to 11:20 a.m. and 3:15 p.m. to 3:45 p.m. On April 3, 2020, oral presentations from the public will be scheduled between approximately 11 a.m. to 11:30 a.m. Those individuals interested in making oral presentations should notify the contact person and submit a brief statement of the general nature of the

evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before March 16, 2020. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by March 17, 2020.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Christina Vert (see FOR FURTHER INFORMATION CONTACT) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at:

<https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: February 7, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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